REMARKS

I. Status of Claims

Claims 3-6, 9-10, 12-15, 28-29, 31, and 33-36 are pending. Claim 9, 12, and 33 are independent. Claims 9, 12, 15, and 33 are amended.

Claims 33-36, 3-6, 10, 28, 29, and 31 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

Claims 12, 14-15, 31, 33-35, 4-6, 9 and 10 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,203,551 to Wu in view of U.S. Patent No. 4,598,006 to Sand. Claims 12, 14-15, 31, 33-35, 4-6, 9, and 10 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sand in view of Wu. Claims 12, 14-15, 31, 33-35, 4-6, 9, and 10 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable in view of Sand/Sand in view of Wu, further in view of U.S. Patent No. 5,527,337 to Stack et al. Claims 3, 9, 13, and 28-29 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al./Sand in view of Wu further in view of Stack et al, and further in view of U.S. Patent No. 6,495,204 to Allen et al. Claims 6, 10, and 36 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al., and further in view of U.S. Patent No. 6,627,246 to Mehta et al.

II. Rejections under 35 U.S.C. § 112

Claim 33 stands rejected under §112, 2nd paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In response, the undersigned submits that the claim is amended to correct any perceived ambiguity.

III. Rejections under 35 U.S.C. § 103 and Request for Reconsideration

Independent claims 9, 12, and 33 stand rejected as allegedly being unpatentable over U.S. Patent No. 6,203,551 to Wu in view of U.S. Patent No. 4,598,006 to Sand.

The undersigned submits that claim 9 is patentable over Wu '551/ Sand '006 at least because it recites, "...a method of coating a stent ... causing the stent ... to be in contact with the supercritical fluid ... collecting the supercritical fluid after transferring the therapeutic."

The undersigned submits that claim 12 is patentable over Wu '551/Sand '006 at least because it recites, "...a method of coating a medical device...swelling the coating on the medical device with a supercritical fluid devoid of coating."

The undersigned submits that claim 33 is patentable over Wu '551/Sand '006 at least because it recites, "...a method of coating a stent...swelling the carrier coating with a supercritical fluid devoid of therapeutic."

Essentially, the Office Action contends that Wu discloses a method of preparing a stent that includes the step of swelling a coating on the stent during its preparation but fails to teach the use of supercritical fluids. The action further contends that Sand teaches the use of supercritical fluid to pre-swell a coating prior to interjecting therapeutic into the coating. Relying on these conclusions, the Office Action contends that it would have been obvious to modify the coating process of Wu to include swelling or pre-swelling a coating on a stent with a supercritical fluid.

This argument fails for several reasons. These include that: (a) Sand is not analogous art; (b) that Sand does not disclose the pre-swelling of a coating with supercritical fluid; and, (c) that it is not viable to use a supercritical fluid in the Wu system as argued because the high pressures associated with supercritical fluids would be unworkable in the Wu system.

Wu is entitled "Chamber For Applying Therapeutic Substances to an Implant," and regards a system that allows a practitioner to treat a metallic stent positioned on a dilation balloon just prior to the deployment of the stent. *See, e.g.*, Figs. 3-4 and col. 4:62-64 (noting "the user then removes chamber 40 from balloon 26, and performs the implantation procedure.") It does this through the use a two hemisphere chamber placed around a stent positioned on a balloon. The Office Action recognizes that "Wu fails to teach that SCF can be used as a solvent in a swell loading process." The Office Action endeavors to meet this shortcoming through the use of Sand. Sand is entitled, "Method For Impregnating a Thermoplastic Polymer." It regards

"a method for impregnating a thermoplastic polymer with an impregnation material such as a fragrance or pest control agent." *See,* Abstract. Sand is not analogous art and may not be used in an obviousness rejection. Sand regards uncoated thermoplastic, it does not regard methods for treating coatings of medical devices and coatings of stents as in the claims. It is also not endeavored to problems that may arise in treating coatings. Consequently, Sand may not properly be considered analogous art.

Even if Sand is considered analogous art, which it is not, the claims are patentable over Wu and Sand. As to claim 9, it is at least patentable over Wu and Sand because neither discloses or suggests causing a stent to be in contact with a supercritical fluid and therapeutic as in the claim. The Office Action recognizes that Wu doesn't disclose SCFs and seeks to fill this discrepancy by citing to Sand. However, modifying the Wu process to include SCFs is not plausible, regardless of what may be taught by Sand. The Wu process is a process performed by a practitioner nearly contemporaneous with the deployment of a stent. The device used in Wu to contain a solvent is a small device placed around the stent and balloon. The pressures associated with SCFs exceed 1,000 psi. The Wu device is incapable of functioning under these pressures, it would simply blow apart. Moreover, even if it were capable, such high pressures would destroy the delivery balloons positioned within the chamber, crushing them. Still further, for argument sake, if the balloon were made to resist these crushing pressures, they would be impossible to inflate in a patient. All these show that it is not obvious to modify Wu's process to include the use of SCFs.

Still further, there is also no motivation in the cited references to modify Sand to include the collection and/or removal steps recited in the claim. It appears that Official Notice is also being utilized to support the rejections of claim 9. Applicant respectfully traverses the Official Notice taken and requests evidence to substantiate the alleged motivations to modify Sand. Specifically, Applicant respectfully requests evidence to substantiate the theory that it would have been obvious to one having ordinary skill in the art to have collected and removed therapeutic as required by the claims. Such support is required under MPEP 2144.02 and 2144.03. Sand, by the Examiner's own admission, does not disclose these steps, and unsupported allegations cannot be used to reject the claims.

As to claim 12, it is patentable over Wu and Sand at least because neither discloses or suggests swelling a coating with a supercritical fluid devoid of coating as in the claim. Sand doesn't address swelling a coating with a SCF. None of the cited passages mention a coating and the undersigned could find no other reference in Sand to a coating.

Even if Sand did address a coating, it fails to address the notion of pre-swelling as contended by the Office Action. The portion of Sand cited for causing "the polymer to swell so that a pharmaceutical would be added to the swollen polymer" does not disclose the use of SCFs as agued by the Office Action. Example 1 of Sand says that an autoclave is pumped to an "intermediate" temperature prior to directing a compressed feed of CO2 to the autoclave. *See* Col. 5:10-25. The definition of intermediate is never provided, however, throughout Sand it is repeatedly discussed that the impregnated fluid in a SC state is what causes the thermoplastic to swell and not a prior interface between SCF and the thermoplastic. Thus, reading intermediate to mean a pressure sufficient to place the CO2 in a supercritical state, as is argued by the Office Action, is contrary to the direct language of Sand. Accordingly, Sand doesn't contain a disclosure or suggestion to swell a coating as in the claim and even if it did, it would be improper to combine it with Wu as mentioned above, because Sand is not prior art and because Wu is not workable with SCFs.

As to claim 33, it is patentable over Wu and Sand at least because it recites swelling the carrier coating with a supercritical coating devoid of therapeutic. As discussed above, a close reading of Sand shows that the portion cited in the Office Action may not properly be read as disclosing this claim language. There is no reason to assume the intermediate pressures recited in the quoted passage of Sand are supercritical pressures; even if they were, the claim is still patentable for the other reasons addressed above.

For at least these reasons, claims 9, 12, and 33 and their dependent claims are patentable over Wu and the cited references.

IV. Conclusion

In view of the above amendments and remarks, it is believed that the above-identified application is in condition for allowance, and notice to that effect is respectfully requested. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned at the telephone number indicated below.

The Commissioner is authorized to charge any fees or credit any overpayments which may be incurred in connection with this paper under 37 C.F.R. §§ 1.16 or 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

Date: September 12, 2006

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